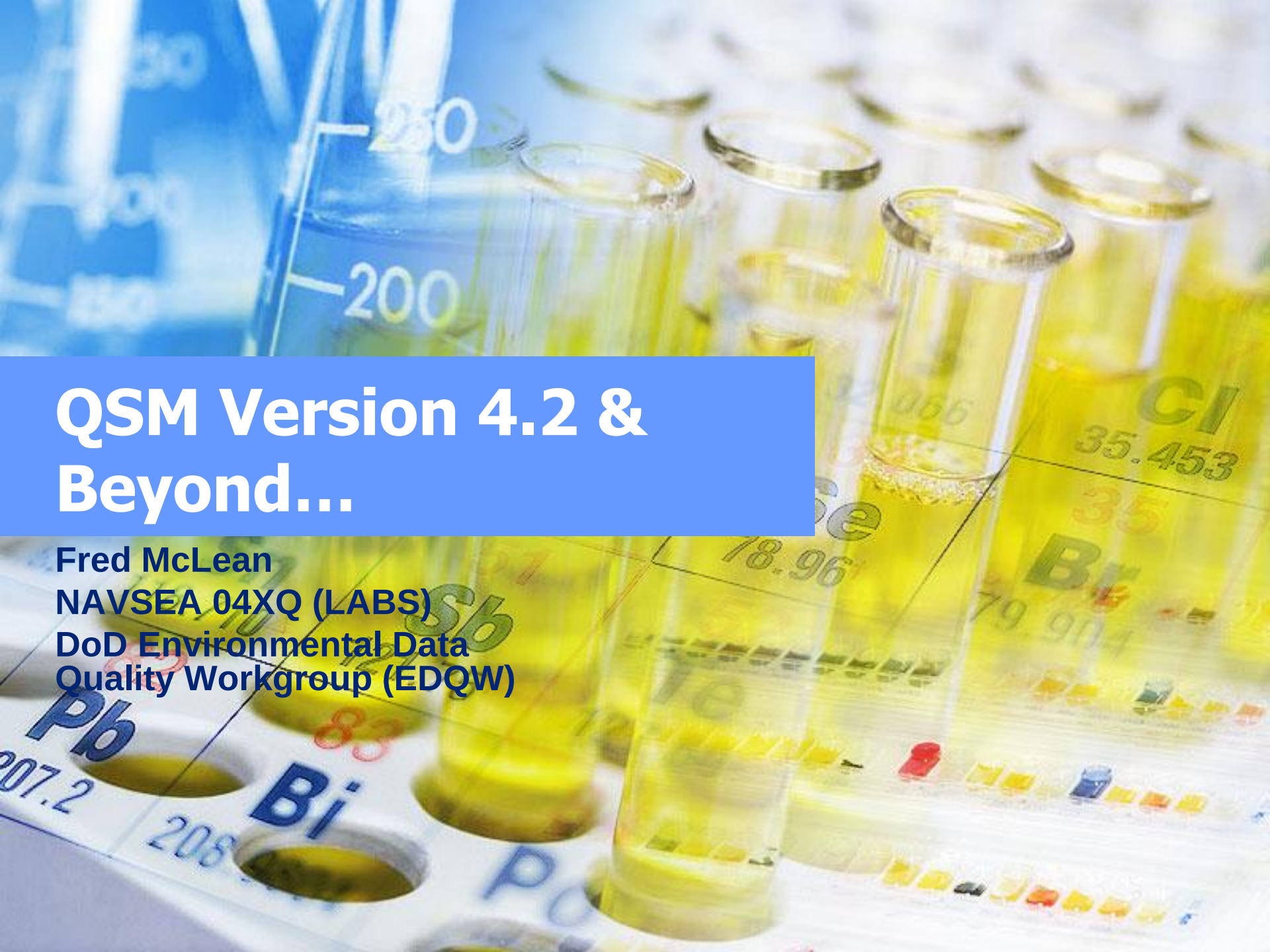

QSM Version 4.2 & Beyond…

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Agenda

- Final changes to the QSM for version 4.2
- Frequently Asked Questions (FAQs) & how you can help
- Proposed future of the QSM
- Wrap-up & Questions

QSM Version 4.2

Gray Box 14

Control of Records: Date and Time (Requirement)

Both date and time of preparation and analysis are considered essential information, regardless of the length of the holding time, and shall be included as part of the laboratory report. If the time of the sample collection is not provided, the laboratory must assume the most conservative time of day (i.e., earliest). For the purpose of batch processing, the start and stop dates and times of the batch preparation shall be recorded.

QSM Version 4.2

Gray Box 15

Internal Audits: Schedule and Personnel (Requirement)

The audit schedule shall ensure that all areas of the laboratory are reviewed over the course of one year. Audit personnel shall be trained and qualified in the specific quality system element or technical area under review. Laboratories shall determine the training and qualification requirements for audit personnel, including quality managers, and shall establish procedures to ensure that audit personnel are trained and qualified (i.e., have the necessary education and/or experience required for their assigned positions). These requirements and procedures must be documented.

QSM Version 4.2

Gray Box 20

Environmental Test Methods and Method Validation: Annual Reviews (Requirement)

All technical SOPs (e.g., sample preparation, analytical procedures, sample storage, sample receipt, etc.) shall be reviewed for accuracy and adequacy annually and whenever method procedures change, and updated as appropriate. All such reviews shall be documented and made available for assessment.

(Guidance)

Non-technical SOPs that are not required elements of the quality manual (e.g., personnel policies, timekeeping procedures, payroll, etc.) are considered Administrative SOPs and are not required to be reviewed annually.

QSM Version 4.2

Gray Box 21

Environmental Test Methods and Method Validation: Modifications to Published Methods (Clarification)

~~Where published methods are specified as required for a project, requirements contained within that method shall be followed.~~

Method modifications include a change of stoichiometry, technology or change in quality control acceptance criteria as defined in the appropriate Appendix F table or the method.

QSM Version 4.2

Gray Box 23

Environmental Test Methods and Method Validation: Target Analytes (Requirement)

The laboratory shall analyze those target analytes identified by the client on a project-specific basis. Laboratories will analyze for analytes that are within their scope of accreditation. If the project does not specify analytes, the laboratory must communicate the list of analytes within their scope to the DoD project. If the project requires analytes that are not within the laboratory's scope of accreditation, the laboratory must become accredited for the specific analytes or testing must be performed by another DoD ELAP accredited laboratory.

QSM Version 4.2

Gray Box 24

Environmental Test Methods and Method Validation: Demonstration of Capability (Requirement)

Appropriate Demonstration of Capability Techniques include the following:

Testing of reference standards or reference materials;

Comparison of results to those achieved using other validated, standard methods; and interlaboratory comparisons

QSM Version 4.2

Gray Box 29

Environmental Test Methods and Method Validation: Manual Integrations (Requirement)

The person performing the manual integration must sign and date each chromatogram and document the rationale for performing manual integration (electronic signature is acceptable). Records for manual integrations may be maintained electronically as long as all requirements, including signature requirements, are met and the results can be historically reconstructed.

QSM Version 4.2

Gray Box 30

Environmental Test Methods and Method Validation: Software Verification (Requirement)

At a minimum, a sample data set shall be used to test and verify the operation of all automated data reduction processes (including data capture, manipulation, transfer, and reporting). This shall be done any time new software (including commercially available software, such as Chemstation) is installed or programming code is modified or manipulated.

QSM Version 4.2

Gray Box 31

Support Equipment Table:

Analytical balance: ± 0.1% or ± 0.5 mg whichever is greater

Monitoring of refrigerator/ freezer temperature: Daily (i.e., 7 days per week; (MIN/MAX thermometers allowed)

QSM Version 4.2

Gray Box 36

Equipment: CCV Acceptance Criteria (Requirement)

The concentration of the CCV standard shall be between the low calibration standard and the midpoint of the calibration range

(Guidance)

The source of the CCV standard should be the same as the source for the initial calibration standard(s).

QSM Version 4.2

Gray Box 37

Equipment: Corrective Action for Noncompliant CCV (Requirement)

If these data are reported, the data must be qualified and explained in the case narrative.

If the laboratory routinely analyzes two CCVs, then both CCVs must be evaluated. If either CCV fails, perform corrective actions as required by NELAC Section 5.5.10 and reanalyze all samples since last acceptable calibration verification.

QSM Version 4.2

Gray Box 43

Proficiency Testing (PT) Program (Requirement)

Initial or Continuing PT Studies

For continuing acceptance, completion dates of successive proficiency rounds for a given field of proficiency testing shall be approximately six months apart, where practicable.

QSM Version 4.2

Gray Box 47

Reporting the Results: Use of Data Qualifiers

(Guidance) *Example: Detection limit (DL) = 2,

Limit of Detection (LOD) = 4, Limit of Quantitation (LOQ) = 15, sample is undiluted.

Sample #1: Analytical result: Not detected; Reported result: :<4 or 4 U

QSM Version 4.2

Gray Box C-2

Initial Test Method Evaluation: QC Requirements for Non-Standard Methods (Requirement)

The laboratory must evaluate non-standard methods (including laboratory-developed methods) using quality control procedures and acceptance criteria that are consistent with those of similar standard methods or technology. Methods that are not published in Standard Methods for the Examination of Water and Wastewater or by recognized entities such as USEPA, USDOE, ASTM, NIOSH, etc., are considered non-standard methods.

QSM Version 4.2

Gray Box D-2

Positive and Negative Controls: LCS Spiking Compounds (Requirement)

All target analytes must be spiked in the LCS (with the exception of PCB analysis, which is spiked per the method). Target analytes are identified by the client on a project-specific basis. This may require the preparation of multiple LCSs to avoid interferences.

Marginal Exceedances (MEs) are allowed for the purpose of DoD ELAP accreditation. MEs are not allowed for target analytes as identified by a project without project specific approval.

QSM Version 4.2

Gray Box D-3

Positive and Negative Controls: LCS Control Limits (Requirement)

Control charts shall be maintained and used to detect trends and prevent out-of-control conditions. Control limits shall be continually monitored for shifts in mean recovery, changes in standard deviation, and development of trends. The laboratory may use the DoD LCS limits (Appendix G) for the purpose of batch control; however, it must also generate in-house limits for the purpose of detecting trends in its processes. Laboratories may choose representative compounds for control charts for the purpose of trend analysis.

QSM Version 4.2

Gray Box D-13

Limit of Detection (LOD): Determination and Verification (Requirement)

Establish the LOD by spiking a quality system matrix at approximately two to three times the detection limit (for a single-analyte standard) or greater than one to four times the detection limit (for a multi-analyte standard).

The LOD must be reported for all methods unless it is not applicable to the test or specifically excluded by project requirements.

DoD recognizes the terms used in the current version of Multi-Agency Radiological Laboratory Analytical Protocols (MARLAP) to describe the detection capabilities of radiological methods.

QSM Version 4.2

Gray Box D-14

Limit of Quantitation (LOQ): Establishment and Verification (Requirement)

For DoD projects, the LOQ must be set within the calibration range (this includes the low calibration point) prior to sample analysis. At a minimum, the LOQ must be verified quarterly.

For radiological testing, DoD recognizes the terms used in MARLAP to describe the quantification capabilities of analytical methods (Minimum Quantifiable Concentration).

Frequently Asked Questions (FAQs)

- Frequently Asked Questions (FAQs) can be viewed on the Navy Labs website: www.navylabs.navy.mil
- To date, close to 90 responses have been addressed
- Responses are based on Environmental Data Quality Workgroup (EDQW) consensus

FAQs (cont.)

How can you help?

Be clear and concise with your questions

Link questions to specific Gray Boxes

NELAC text is not addressed

Explanatory text is always helpful, but…

Make sure there is a question for us!

Be careful with “examples;” make them realistic

FAQs–Some Recent Examples…

Question: For methods that require periodic blank analysis (CCB) such as ICPAEs and ICPMs, if the laboratory routinely analyzes multiple CCBs for the blank check every 10 samples, are they required to evaluate all CCBs as they are for multiple CCVs?

EDQW Response: Yes. All CCBs must be evaluated, just as all CCVs are required to be evaluated.

FAQs–Some Recent Examples…

Question: When interpreting multiple ICAP calibrations in a method would it be correct to consider each element individual as the instrument does. Let's say you are analyzing for As, Cd, Ba, Mo, Tl, and Ni and the molybdenum ICV failed high. The ICALs for As, Ba, Tl and Ni are still acceptable, correct?

EDQW Response: For interpreting data, each ICV metal would be evaluated separately. The ICALs for the passing metals would still be acceptable, but any ICV failures would require re-calibration for those metals that failed.

FAQs–Some Recent Examples…

Question: The dechlorinating agent for 8151 Herbicides water is listed as sodium thiosulfate. Our experience with this is that it causes an adverse chemical reaction, forming a precipitate that causes a great deal of interference. Our lab would prefer to use ammonium chloride, as this seems to cause the least amount of background interferences. What would be your stance on this as a substitute dechlorinating agent?

EDQW Response: As you stated, sodium thiosulfate is the required preservative for Herbicide Method 8151. The method specifies the use of sodium thiosulfate because it is a strong reducing agent (used for the removal of chlorine). Ammonium chloride is not considered a strong reducing agent. If the laboratory wishes to use ammonium chloride, this would be considered a method modification and a validation study must be performed to demonstrate the effectiveness of the dechlorinating agent.

FAQs–Some Recent Examples…

Question: Table: Calibration Blank Acceptance Criteria states "No analytes > LOD." Clarification requested on 'LOD.' Is the term LOD use here the numerical LOD from the statistical LOD study (MDL/DL Study) or is it the numerical LOD from the verification sample (Box D-13)?

EDQW Response: When LOD is mentioned in the Tables, it refers to the verified LOD. The detection limit (not LOD), is determined numerically. The spike concentration of a successful verification becomes the LOD.

- *Example:* Numerically determined DL is 2. LOD is established by spiking a standard at 4. If the result meets the criteria listed in D-13, the reported LOD is 4.

FAQs–Some Recent Examples…

Question: Can the LOD = the MDL if the true value of the LOD verification spike is equal to the MDL and meets the signal to noise criteria?

EDQW Response: While this is technically allowed, this is not the intent of the QSM. Equating the LOD and DL either results in an artificially inflated DL or an unsustainable LOD. Either of these conditions may result in the laboratory providing data that is not suitable for the project's intended use.

The QSM and the Future…

What does the future hold for the QSM?

- Not intending to produce more version 4.x's
- Working with DOE to create a combined Quality Systems document (DoD QSM and DOE QSAS)
- Expect by 2012 EMDQ to have a draft document

What will this document look like?

- Will be based on the 2009 TNI standard and ISO 17025:2005
- Will NOT include ISO text due to copyright issues
- Unknown at this time if we will have a stand-alone document or combined with TNI text

What about the DoD and DOE Lab programs?

No changes are expected in the DOD-ELAP or DOECAP programs themselves

The QSM and the Future…..

What has been done so far?

- Identified common gray boxes for inclusion in new document
- Combined DoD & DOE gray boxes in the Quality Systems module
- Identified gray boxes for deletion due to changes in ISO/TNI text
- Identified a few areas that may remain specific to DoD or DOE

Named the combined document:

- Quality Systems Manual for Analytical Services (QSMAS)

Wrap-up

Questions???

We have answers*

Workshop participants are invited to ask questions of the EDQW in the open forum session on Friday, April Fool's Day from 8:00 – 11:00 am